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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,165	09/03/2003	Tsuneco Yasuma	2689US1P	1548

23115 7590 07/28/2005

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
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EXAMINER

DAVIS, ZINNA NORTHINGTON

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/662,165

Applicant(s)

YASUMA ET AL.

Examiner

Zinna Northington Davis

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-37 is/are pending in the application.
4a) Of the above claim(s) 7-9, 19, 21, 22 and 26-36 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6, 10-18, 24, 25 and 37 is/are rejected.
7) ☐ Claim(s) 23 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 10/204,593.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/2003.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-19 and 21-37 are pending.
2. In the response filed May 23, 2005, Applicants have elected Group III, claims 1-18, 23-25, and 37 (all in part). The compound of Example 33 on page 127 is the preferred species.
3. Claims 1-6, 10-18, 23-25, and 37 are readable on the elected species. Claims 7-9, 19, 21, 22, and 26-36 are withdrawn from consideration.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

4. Claims 1-6, 10-18, 23, 24, 25, and 37 are Markush claims which are generic to the elected invention. These Markush claims lack unity of invention. Accordingly, the Markush type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. See MPEP 803.02.

5. Claims 1-6, 10-18, 23, 24, 25, and 37 are objected on the grounds that the claims are drawn to an improper Markush group. In re Harnisch, 206 USPQ 300, states that a unity of invention exists where compounds included within a Markush group(1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. In the instant case, the claimed subject matter does not share a substantial structural feature disclosed as being essential to that utility.

The requirement for a proper Markush claim is that it includes only substances that in their physical, chemical and physiological characteristics are functionally equivalent. The members of the instant Markush groups possess widely different, physical and chemical properties. The compounds are not considered functionally equivalent and are so diverse that they demonstrate dissimilar and unrelated properties. The mere fact that there is structural similarity in pharmaceutical agents is not in itself reason to render all the embodiments functionally equivalent.

The improper Markush group is R.

6. The examined subject matter is as follows:

A compound of formula (I) wherein R represents an optionally substituted heterocyclic group. All other radicals are defined according to claim 1. Amending the claims to the examined subject matter would overcome the improper Markush objection.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 37 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating certain disease states, does not reasonably provide enablement for the prevention of the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to prevention the invention commensurate in scope with these claims.

The recitation of the phrase "preventing or treating inflammatory diseases" is broader than the scope of enablement. It is suggested that the claim should be

Art Unit: 1625

amended to read as --A method for making a pharmaceutical composition for treating inflammatory diseases ... ---. As such, the claim as presented is rejected under 35 U.S.C. 112, first paragraph.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is suggested that the term "general" should be deleted.

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-6 and 10-18 are rejected under the judicially created doctrine of double patenting over claims of U. S. Patent No. 6,654,476 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: alk = methylene; X= direct bond; and R is a heterocyclic group.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

13. The Information Disclosure Statement filed September 9, 2003 has been considered. The references alone or in combination form do not teach nor suggest structurally similar compounds as those instantly claimed. The closest prior art reference is Reference A3. The difference between the prior art compound and the instantly claimed compound is at the G position (carbonyl versus alkoxy). Based upon the definition of G in the specification and examples, there is no teaching or motivation to modify the prior art compounds to derive those instantly claimed. Accordingly, no rejections based upon prior art are made.

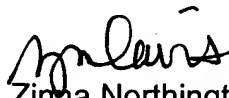
14. Claim 23 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1625

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.

16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Zinna Northington Davis
Primary Examiner
Art Unit 1625